Paper No. 17

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte PREET M. CHAUDHARY

Appeal No. 2002-1802
Application No. 08/490,187

ON BRIEF

Before WINTERS, ADAMS, and GREEN, Administrative Patent Judges.

GREEN, Administrative Patent Judge.

VACATUR AND REMAND TO THE EXAMINER

On consideration of the record, we find that this case is not susceptible to meaningful review and is not in condition for a decision on appeal. Accordingly, we vacate the pending rejection and remand the application to the examiner to consider the issues discussed herein and take appropriate action not inconsistent with the views expressed herein. Lest there be any misunderstanding, the term "vacate" in this context means to set aside or void. When the Board vacates an examiner's rejection, the rejection is set aside and no longer exists. Cf. Ex parte Zambrano, 58 USPQ2d 1312, 1313 (Bd. Pat. App. & Int. 2001).

BACKGROUND

The claims are drawn to a method of detecting the presence or predisposition of an ectodermal disorder or to a method for modulating the functional expression of a TAJ gene or gene product in a cell. Claims 1-21 are pending, and stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with it is most nearly connected, to make and/or use the invention. The examiner relies upon no prior art.

Claims 1 and 9 are representative of the claims on appeal, and are reproduced below.

1. A method for detecting the presence of or predisposition to an ectodermal disorder comprising the steps of:

    a) detecting the presence of a human TAJ gene or gene product in a cell;

    b) correlating the presence of the TAJ gene or gene product with a presence of or predisposition to an ectodermal; disorder.

9. A method for modulating the functional expression of a TAJ gene or gene product in a cell comprising the step(s) of:

    contacting a cell with an agent which specifically binds and modulates the functional expression of a human TAJ gene or gene product, wherein:

    a. the cell is an ectodermal cell; or

    b. the cell is a germ cell which gives rise to progeny ectodermal cells and the method further comprises the step of detecting the functional expression of the TAJ gene or gene product of the progeny cells.

VACATUR AND REMAND

The board serves as a board of review, not a de novo examination tribunal. See 35 U.S.C. § 6(b) ("The [board] shall, on written appeal of an applicant, review adverse decisions of examiners upon applications for patents."). The burden is on the examiner to set forth a prima facie case of unpatentability. See In re Alton, 76 F.3d 1168, 1175, 37 USPQ2d 1578, 1583 (Fed. Cir. 1996). Findings of fact and conclusions of law must be made in accordance with the Administrative Procedure Act, 5 U.S.C. 706 (A), (E) (1994). See Zurko v. Dickinson, 527 U.S. 150, 158, 119 S.Ct. 1816, 1821, 50 USPQ2d 1930, 1934 (1999).

Claims 1-21 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

According to the rejection:

> The instant specification discloses a "TAJ" nucleic acid sequence and protein sequence (SEQ ID NO:1 and 2). The specification discloses at page 1 that there are over 150 different ectodermal dysplasia syndromes. The specification discloses at page 3 that ectodermal disorders may arise from temporal, developmental, quantitative or qualitative TAJ misexpression and that a wide variety of causalities may effect such misexpression such as genetic lesions or mutations gene itself or direct or indirect TAJ gene regulatory sequences, the misexpression of genes or gene products which may in turn regulate TAJ expression or TAJ function, etc.

* * *

> The instant specification does not provide sufficient guidance or examples that would show by correlation the practice of the instant invention without undue experimentation. Since there are so many (over 150) disease states and little guidance for one of skill in the art to detect or treat such diseases based on the instant specification one would be left to undue trial and error and experimentation. . . . The instant specification appears to be an invitation for one in the art to draw correlations to any nucleic acid sequence or protein that might be a TAJ to the numerous disease states contemplated. This is not a simple task considering the large number of diseases that manifest in numerous different ways in different cells and involve different biological pathways. For example, ectodermal disorders may arise from temporal, developmental, quantitative or qualitative TAJ misexpression and that a wide variety of causalities may effect such misexpression such as genetic lesions or mutations gene itself or direct or indirect TAJ gene regulatory sequences, the misexpression of genes o gene products which may in turn regulate TAJ expression or TAJ function, etc and one of skill in the art is left to make these correlations themselves. Claim 1 recites that a correlation must be made. The instant specification has essentially demonstrated that SEQ ID NO:2 activates the JNK pathway upon over expression and that hTAJ is expressed in prostate cell and fetal kidney cells (fetal kidney cell line) and that TAJ is differentially expressed in murine fetuses. The information provided in the Tables is unclear as to how it provides evidence for TAJ association in ectodermal dysplasia. Without this knowledge or correlative evidence or guidance it is unclear how one of skill in the art could practice the claimed invention without undue trial and error experimentation.

Examiner's Answer, pages 3-5.

The above rejection suffers from several deficiencies. First, it does not separately discuss the two independent claims, which are drawn to very different methods. Claim 1 is drawn to a method for detecting the presence or predisposition to an ectodermal disorder, i.e., a diagnostic method. Claim 9 is drawn to a method for modulating the functional expression of a TAJ gene or

gene product in a cell, i.e., a therapeutic method. The analysis as set forth in the rejection, however, is focused on the method of claim 1 and does not appear to specifically address the method of claim 9.

Second, neither the examiner nor appellant appears to have addressed on the record how claim 1 should be construed. Claim 1 recites "[a] method for detecting the presence of or predisposition to an ectodermal disorder comprising . . . detecting the presence of a human TAJ gene or gene product in a cell" and "correlating the presence of the TAJ gene or gene product with a presence of or predisposition to an ectodermal disorder."

The claim reads on detecting the presence of any human TAJ gene or gene product in a cell, including a normally expressed TAJ gene or gene product. The specification, however, teaches that "[t]he invention provides methods and compositions for diagnosing and treating ectodermal disorders associated with misexpression of a TAJ gene." Id. at 1 (emphasis added). Upon remand, when addresssing the enablement issue, both the examiner and appellant may want to address the scope of claim 1 and how it relates to the possibility of detecting normal expression of a TAJ gene or gene product and if the specification teaches how one skilled in the art may use the normal expression to detect the presence of or predisposition to an ectodermal disorder.

Finally, we would like to point the examiner's attention to Enzo Biochem Inc. v. Calgene, Inc., 188 F.3d 1362, 52 USPQ2d 1129 (Fed. Cir. 1999) as an example of the factors to be considered and the analysis that should be

undertaken in determining whether the specification enables one skilled in the art to make and/or use the claimed invention.

OTHER ISSUES

The examiner may also wish to consider whether the claims contain subject matter that is not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention, i.e., lack of adequate written description.

Although the claims are not drawn to a nucleic acid sequence per se, claim 1 requires one to detect the presence of a human gene or gene product in a cell, and claim 9 requires one to regulate the expression of a TAJ gene or gene product in a cell. Therefore, the methods require knowledge of a gene sequence, and we look to the cases that address what constitutes an adequate written description for a claim drawn to a nucleic acid sequence.

In Enzo Biochem, Inc. v. Gen-Probe Inc., 296 F.3d 1316, 63 USPQ2d 1602 (Fed. Cir. 2002), the court adopted a portion of the Guidelines proffered by the United States Patent and Trademark Office (USPTO). The court stated that:

> The written description requirement can be met by "showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics . . . i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of characteristics.

Enzo Biochem, 296 F.3d at 1324, 63 USPQ2d at 1613 (citations omitted).

The court also addressed the issue of what constitutes adequate written description of a claim to a broad genus of sequences. In The Regents of The University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1998), the court determined that the disclosure of rat cDNA did not provide adequate written description support for claims drawn to mammalian and vertebrate DNA. Eli Lilly, 119 F.3d at 1567-68, 43 USPQ2d at 1405. The court stated:

> In claims to genetic material, however, a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is.

Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406.

In Enzo-Biochem, the court refined the approach advanced by Eli Lilly, adopting an example offered in the USPTO guidelines having facts that contrasted with those of Eli Lilly, wherein the written description requirement would be met. Thus, adequate written description may be present for a genus of nucleic acids based on their hybridization properties, "if they hybridize under highly stringent conditions to known sequences because such conditions dictate

that all species within the genus will be structurally similar." Enzo Biochem, 296 F.3d at 1327, 63 USPQ2d at 1615.

In this case, the specification teaches the sequences of the full-length TAJ cDNA and protein sequences, and then gives thirteen examples of genetic lesions show to be associated with an ectodermal dysplasia. See Specification, page 3, Table 1. The claims, however, are not limited to those specifically disclosed genetic lesions, nor do the claims limit the nucleic acid sequences required to practice the claimed methods to a sequence that is structurally related to the disclosed sequences. Thus, upon return of the application, the examiner may want to address the scope of the nucleic acid sequences required to practice the claimed method, and whether the disclosure as filed provides adequate written description support for those sequences.

FUTURE PROCEEDINGS

The case is being returned to the jurisdiction of the examiner for further action. Upon receipt, the examiner should address the patentability of the claims in accordance with this opinion. If prosecution is resumed, we state that we are not authorizing a supplemental examiner's answer under 37 CFR § 1.193(b)(1).

VACATED and REMANDED

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